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URGENT FIELD SAFETY NOTICE
PRODUCT RECALL - ACTION REQUIRED
FCA-83
Fogarty Adherent Clot Catheter
Model Numbers: 1408010 and 140806; Lot Numbers: 60439817 and 60439818

<MM DD, YYYY>

<Customer #>
<Contact Name or Dept.>
<Firm Name>
<Attention: **RISK** MANAGEMENT>
<Address>
<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, we are always monitoring our products throughout their life cycle to quickly identify and correct issues. We recently discovered an issue with a product and are initiating a recall.

Action to be taken: Werequest that you return any units that are currently in your inventory with the model and lot numbers referenced above. For your convenience, we have pre-populated the attached acknowledgement form with the affected lots you received. Please follow the instructions in the attached acknowledgment form to complete the recall process.

Details on affected devices: The Fogarty ACC catheters are designed to effectively remove clot material in the peripheral vasculature. The catheters are indicated for the removal of emboli and thrombi trom native arteries or synthetic grafts. The devices are designed to facilitate clots too resistant to be removed by an elastomeric balloon. The device features a spiral,..shaped, latex-covered stainless steel cable that assumes a corkscrew shape when retracted, greatly expanding the surface area to entrap fibrous material. The device is 80 cm in length, available in French sizes 4F-6F and applicable membrane diameters of 6mm to 10mm.

Description of the problem: The diameter of the affected Fogarty Catheter balloon, measures 6mm instead of 10mm. We have idenlified the root cause of this issue and have implemented actions to prevent its reoccurrence. lf a smaller size catheter is used, theballoon may fail tomakecontact with the vesselwal! during balloon modulation. The clinician will need to exchange the catheter for a larger size, causing a slight delay in treatment, there is no information to suggest this issue may risk patient health or safety.

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of surgical and critical care patients. This commitment extends to the products, services, and support we provide. We apologize for the inconvenience caused by this action and appreciate your attention to this matter.

Edwards has communicated this Field Safety Notice to the appropriate regulatory authorities.
lf you have additional questions, please call Edwards Customer Service at **XXXX.XXXX.**

Sincerely,

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Acknowledgment Form

<Customer #>
<Contact Name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Please follow all instructions below to complete the recall process.

Step 1. Complete this acknowledgement form with the following information:

- Verify your inventory
- Complete all seclions of the table below, indicate "O" if you have no product to return
- Fax the completed form to Edwards Customer Service at 1-800-422-9329, within 3 days from receipt of this notification

Step 2. If you have unused products, Customer Service will contact you to arrange their return.

Product Number /Model	Customer	Lot Number	**Quantity** Shipped From **EW**	**UOM**	Order Number	**Date** Shipped from EW	**Number** of units to be returned	**RGA** Number
	-.	..				...		

Name (Print):_____

Telephone Number: _____

Signature:_____

Date:_____